

suitable for such formulations include the following: fillers and extenders (e.g., starch, sugars, mannitol, and silicic derivatives); binding agents (e.g., carboxymethyl cellulose and other cellulose derivatives, alginates, gelatin, and polyvinyl-pyrrolidone); moisturizing agents (e.g., glycerol); disintegrating agents (e.g., calcium carbonate and sodium bicarbonate); agents for retarding dissolution (e.g., paraffin); resorption accelerators (e.g., quaternary ammonium compounds); surface active agents (e.g., cetyl alcohol, glycerol monostearate); adsorptive carriers (e.g., kaolin and bentonite); emulsifiers; preservatives; sweeteners; stabilizers; coloring agents; perfuming agents; flavoring agents; lubricants (e.g., talc, calcium and magnesium stearate); solid polyethyl glycols; and mixtures thereof.

The terms “pharmaceutically or cosmetically acceptable carrier” or “pharmaceutically or cosmetically acceptable vehicle” are used herein to mean, without limitations, any liquid, solid or semi-solid, including but not limited to water or saline, a gel, cream, salve, solvent, diluent, fluid ointment base, ointment, paste, implant, liposome, micelle, giant micelle, and the like, which is suitable for use in contact with living animal or human tissue without causing adverse physiological or cosmetic responses, and which does not interact with the other components of the composition in a deleterious manner. Other pharmaceutically or cosmetically acceptable carriers or vehicles known to one of skill in the art may be employed to make compositions for delivering the molecules of the present invention.

The formulations can be so constituted that they release the active ingredient only or preferably in a particular location, possibly over a period of 25 time. Such combinations provide yet a further mechanism for controlling release kinetics. The coatings, envelopes, and protective matrices may be made, for example, from polymeric substances or waxes.

Methods of in vivo administration of the compositions of the present invention, or of formulations comprising such compositions and other materials such as carriers of the present invention that are particularly suitable for various forms include, but are not limited to, oral administration (e.g. buccal or sublingual administration), anal administration, rectal administration, administration as a suppository, topical application, aerosol application, inhalation, intraperitoneal administration, intravenous administration, transdermal administration, intradermal administration, subdermal administration,

intramuscular administration, intrauterine administration, vaginal administration, administration into a body cavity, surgical administration at the location of a tumor or internal injury, administration into the lumen or parenchyma of an organ, and parenteral administration. Techniques useful in the various forms of administrations above include but are not limited to, topical application, ingestion, surgical administration, injections, sprays, transdermal delivery devices, osmotic pumps, electrodepositing directly on a desired site, or other means familiar to one of ordinary skill in the art. Sites of application can be external, such as on the epidermis, or internal, for example a gastric ulcer, a surgical field, or elsewhere.

The compositions of the present invention can be applied in the form of creams, gels, solutions, suspensions, liposomes, particles, or other means known to one of skill in the art of formulation and delivery of therapeutic and cosmetic compounds. Ultrafine particle sizes of electroprocessed materials can be used for inhalation delivery of therapeutics. Some examples of appropriate formulations for subcutaneous administration include but are not limited to implants, depot, needles, capsules, and osmotic pumps. Some examples of appropriate formulations for vaginal administration include but are not limited to creams and rings. Some examples of appropriate formulations for oral administration include but are not limited to: pills, liquids, syrups, and suspensions. Some examples of appropriate formulations for transdermal administration include but are not limited to gels, creams, pastes, patches, sprays, and gels. Some examples of appropriate delivery mechanisms for subcutaneous administration include but are not limited to implants, depots, needles, capsules, and osmotic pumps. Formulations suitable for parenteral administration include but are not limited to aqueous and non-aqueous sterile injection solutions which may contain antioxidants, buffers, bacteriostats and solutes which render the formulation isotonic with the blood of the intended recipient; and aqueous and non-aqueous sterile suspensions which may include suspending agents and thickening agents. Extemporaneous injection solutions and suspensions may be prepared from sterile powders, granules and tablets commonly used by one of ordinary skill in the art.

Embodiments in which the compositions of the invention are combined with, for example, one or more "pharmaceutically or cosmetically acceptable carriers" or excipients may conveniently be presented in unit dosage form and

may be prepared by conventional pharmaceutical techniques. Such techniques include the step of bringing into association the compositions containing the active ingredient and the pharmaceutical carrier(s) or excipient(s). In general, the formulations are prepared by uniformly and intimately bringing into association the active ingredient with liquid carriers. Preferred unit dosage formulations are those containing a dose or unit, or an appropriate fraction thereof, of the administered ingredient. It should be understood that in addition to the ingredients particularly mentioned above, formulations comprising the compositions of the present invention may include other agents commonly used by one of ordinary skill in the art. The volume of administration will vary depending on the route of administration. For example, intramuscular injections may range in volume from about 0.1 ml to 1.0 ml.

The compositions of the present invention may be administered to persons or animals to provide substances in any dose range that will produce desired physiological or pharmacological results. Dosage will depend upon the substance or substances administered, the therapeutic endpoint desired, the desired effective concentration at the site of action or in a body fluid, and the type of administration. Information regarding appropriate doses of substances are known to persons of ordinary skill in the art and may be found in references such as L.S. Goodman and A. Gilman, eds, The Pharmacological Basis of Therapeutics, Macmillan Publishing, New York, and Katzung, Basic & Clinical Pharmacology, Appleton & Lang, Norwalk, Connecticut, (6th Ed. 1995). One desirable dosage range is 0.01 μ g to 100 mg. Another desirable dosage range is 0.1 μ g to 50 mg. Another desirable dosage range is 0.1 pg to 1.0 μ g. A clinician skilled in the art of the desired therapy may chose specific dosages and dose ranges, and frequency of administration, as required by the circumstances and the substances to be administered. For example, a clinician skilled in the art of hormone replacement therapy may chose specific dosages and dose ranges, and frequency of administration, for a substance such as progesterone, to be administered in combination with the estrogenic and estrogenic modulatory molecules as required by the circumstances. For example, progesterone, and other progestins known to one of skill in the art may be administered in amounts ranging from about 50 μ g to 300 mg, preferably 100 μ g to 200 mg, more preferably 1 mg to 100 mg. Specific dosages and combinations of dosages of estrogenic and estrogenic modulatory molecules and progestins will depend on the route and frequency of